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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,390

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Harold Neal Bramson

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10/10/2008

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1657

NOTIFICATION DATE

DELIVERY MODE

10/10/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,390	<b>Applicant(s)</b> BRAMSON ET AL.	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/18/08.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,7,12-14,19,22-24,28 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) 31-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,12-14,19,22-24,28 and 31-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The RCE Request and amendment received 8/18/08 have been entered and claims 1, 3, 6-7, 12-14, 19, 22-24, 28 are considered here. Claims 31-42 are withdrawn from consideration. The amended title is acceptable.

In view of the amendments to the claims and arguments presented, the rejection of record under 35 USC 112, first paragraph, is hereby withdrawn.

The conventional method of identifying inhibitors of kinases is binding biotinylated-FSBA with the kinase and detecting the binding with fluorography. The point of novelty described is detecting the binding with either LC/MS or a Western Blot rather than with fluorography.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 3, 6-7, 12-14, 19, 22--24, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Young in view of each of T'Jampens, Vanderkerckhove and Lomas.

Young (J of Biological Chemistry) entitled "Pyridinyl Imidazole Inhibitors of p38 Mitogen Activated Protein Kinase Bind in the ATP Site" teaches on page 12118 column 1, a test inhibitor, SB203580, and p38 kinase were incubated with FSBA and ATP to determine the kinase inhibitory activity of SB203580. The FSBA is an ATP analogue that covalently modifies the kinase at lysine 72 and precludes ATP binding. On page 12119 Fig. 3 shows the effect of FSBA on the binding of SB203580 to p38 kinase.

The claims differ from Young in that they include the limitation of using a method of Western blot or mass spec to determine binding of the kinase and analyte rather than fluorography.

T'Jampens (FEBS Letters) entitled "Selected BTB/POZ Kelch Proteins Bind ATP" teaches on page 22 first column determining binding of FSBA and ATP by Western blot analysis.

Vanderkerckove (2006/0160131) entitled "Method for the Identification of Drug Targets" teaches in paragraph 49 using FSBA to target ATP binding proteins, particularly kinases, to produce tagged peptides which are quantified. In paragraph 50 this is performed by MS based techniques. In paragraph 84 localizing the ATP binding site is discussed.

Lomas (2003/0077616) entitled "Biomolecule Characterization Using Mass Spectrometry and Affinity Tags" teaches in paragraph 10, the tagged products are determined by MS. See paragraph 11. In paragraph 183 types of affinity labeling are discussed including FSBA for ATP binding molecules such as kinases. Such affinity labels can be useful for analyzing kinase cascades. In paragraph 199 capture reagents employing biotin are described.

It would have been obvious to one of ordinary skill in the art at the time of the invention to determine binding in the method of Young who teaches a radiolabeled kinase binding assay and determine the binding by Western blot as taught by T'Jampens or MS as taught by each of Vanderkerckove and Lomas because all three are well known methods of determining binding and to employ the methods of T'Jampens, Vanderkerckove or Lomas for their art recognized function with the expected result would have a high expectation of success. To substitute one well known method of determining binding, such as fluorography, with other well known methods of determining binding such as Western blot or MS, would have been obvious and is commonly performed in the enzyme assay art. No unexpected results are seen.

Claims 1, 3, 6-7, 12-14, 19, 22-24, 28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Method claim 1 is written in non-standard terminology and the following is suggested as a broad template only:

1. A method of identifying a test compound that inhibits a kinase having an ATP binding site comprising:

(b) determining binding of biotinylated-FSBA to said ATP binding site of the kinase in the presence and absence of the test compound using mass spectroscopy to obtain a mass peak of the bound biotinylated-FSBA,

(c) determining said unbound test compound and kinase using mass spectroscopy to obtain mass peaks,

(d) comparing the mass peak of said bound biotinylated-FSBA to the ATP binding site of the kinase and mass peaks of said unbound test compound and kinase in the presence and absence of the test compound,

(e) identifying whether said test compound inhibits said ATP binding of the kinase by correlating the mass peaks wherein the test compound diminishes the mass peak of said biotinylated-FSBA bound to said kinase.

In claim 12(a) "the" kinase may be intended.

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The Abstract of the Disclosure is objected to because it is not in proper narrative form and contains legal terminology. Correction is required. See M.P.E.P. § 608.01(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

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Primary Examiner  
Art Unit 1657